

REMARKS

Claims 5, 7, 11, and 14-18 are pending. Applicants have amended claim 5 to specify that the water-soluble calcium salt is “selected from the group consisting of calcium chloride, calcium lactate, and calcium gluconate.” Support for this amendment can be found throughout the specification, e.g., at page 4, line 24 and page 5, line 2. No new matter has been added.

Rejection under 35 U.S.C. § 102(b)

Claims 5, 7, 11, and 15-18 have been rejected as allegedly being anticipated by Iwata *et al.* (WO 01/40182)(hereafter “Iwata”).

Claim 5 as presently amended requires that “the calcium-containing compound is a water-soluble calcium salt selected from the group consisting of calcium chloride, calcium lactate, and calcium gluconate.” In contrast, Iwata does not teach using calcium chloride, calcium lactate, or calcium gluconate. Iwata merely discloses that calcium sulfate and calcium carbonate may be added to a coloring agent. Claim 5 and claims dependent thereon are not anticipated by Iwata because Iwata does not teach every limitation of claim 5. Thus, Applicants respectfully ask the Examiner reconsider and withdraw this ground for rejection.

Rejection under 35 U.S.C. § 103(a)

Claim 14 is rejected as allegedly being obvious over Iwata.

In view of the present amendments to claim 5 (claim 14 depends on claim 5), Applicants respectfully ask the Examiner reconsider and withdraw the rejection.

In addition, Applicants respectfully direct the Examiner's attention to the Declaration of Yukoh Sakata under 37 C.F.R. § 1.132 filed herewith. The Declaration describes the results of tests illustrating the difference in film formation between a composition disclosed in Iwata (“the Iwata composition”) and a composition of the present claims. The Iwata composition includes HPMC and the water-insoluble calcium salt, calcium carbonate. Calcium carbonate has a solubility of 0.0014 g in 100 g of water at 25 °C. The composition within the present claims

includes HPMC and the water-soluble calcium salt, calcium lactate. Calcium lactate has a solubility of 4.8 g in 100 g of water at 25 °C.

As explained in the Declaration, when the composition containing calcium lactate was tested, a lustered, mono-layered white film was formed. When a lustered white film is formed on the surface of a pharmaceutical preparation, the pharmaceutical preparation is protected from visible light- or ultraviolet light-irradiation thereby reducing decomposition. Therefore, the stability and the quality of the pharmaceutical preparation can be maintained as shown in Tables 3 and 4 of the present specification.

In contrast, when the Iwata composition containing calcium carbonate was tested, no lustered film was formed. In fact, only an uneven, two-layered film was observed. The uneven, two-layered film contains an upper layer formed by HPMC coating film and a lower layer formed by agglomerates of calcium carbonate particles. Such a two-layered film can allow light to pass through the agglomerates. As can be seen, Iwata does not teach or suggest a composition that includes a water-soluble calcium salt and can form a lustered, mono-layered film that exhibits light-shielding properties.

The Declaration explains that before being dried, the composition containing the water-soluble calcium salt was a transparent solution, while the Iwata composition containing the water-insoluble calcium salt was a white suspension. It can be understood that the transparent solution can easily be prepared and coated thus preventing the occurrence of problems such as clogging spray nozzles or depositing solid materials at the tips of the nozzles, which may occur in the case of a suspension, e.g., the Iwata composition. Thus, one of ordinary skill in the art would not be motivated, based on the teachings of Iwata (*i.e.*, a white suspension) to prepare a transparent solution for the formation of a white mono-layered film with light-shielding properties.

In view of the foregoing, Applicants submit that the present claims are not obvious over Iwata.

Applicant : Yuko Sakata *et al.*
Serial No. : 10/539,021
Filed : January 30, 2006
Page : 6 of 6

Attorney's Docket No.: 19331-0002US1 / OSP-18070

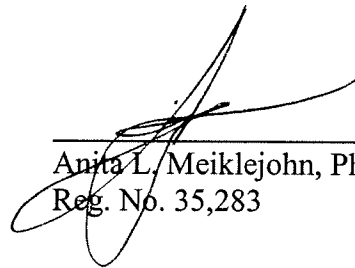
CONCLUDING FORMALITIES

As a courtesy, Applicants send via mail a paper copy of the Declaration of Yukoh Sakata under 37 C.F.R. § 1.132 because the Declaration includes a color photo.

The fee for the Request for Continued Examination is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No. 19331-0002US1.

Respectfully submitted,

Date: 10 MARCH 2009



Anita L. Meiklejohn, Ph.D.
Reg. No. 35,283

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (877) 769-7945